Department of Health Care Services

Proposed May Revision Trailer Bill Language

New Pricing Benchmark for Medi-Cal Drug Reimbursement

Section 14105.45 of the Welfare and Institutions Code is amended to read:

(a) For purposes of this section, the following definitions shall apply:

(1) "Average acquisition price" means the price determined by the department to represent the actual average acquisition purchase price paid for a drug product by retail pharmacies in California. The average acquisition price shall not be considered confidential and shall be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(2) **~~(1)~~** "Average manufacturers price" means the price reported to the department by the Centers for Medicare and Medicaid Services pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8).
~~In the event an average manufacturer's price is not available, the department shall use the direct price as the average manufacturer's price~~.

(3) **~~(2)~~** "Average wholesale price" means the price for a drug product listed as the average wholesale price in the department's primary price reference source.
~~(3) "Direct price" means the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source~~.

(4) "Estimated acquisition cost" means the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.

(5) "Federal upper limit" means the maximum per unit reimbursement when established by the Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

(6) "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, **~~quantity,~~** and dosage form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

(7) "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(8) "Maximum allowable ingredient cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

(9) "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code.

(10) "Non-legend drug" means any drug whose labeling does not contain the statement referenced in paragraph (7).

(11) "Selling price" means the price ~~used in the establishment of the estimated acquisition cost. The department shall~~ base**d** ~~the selling price~~ on the average manufacturer's price plus a percent markup determined by the department to be necessary for the selling price to represent the average purchase price paid by retail pharmacies in California. The selling price shall not be considered confidential and shall be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(12) "Volume weighted average" means the aggregated average volume for **a group of legend or non-legend** ~~generically equivalent~~ drugs, weighted by each drug's percentage of the **group's** total volume in the Medi-Cal fee-for-service program during the previous six months. For purposes of this paragraph, volume is based on the standard billing unit used for the **legend or non-legend** ~~generically equivalent~~ drugs.

(13) "Wholesaler acquisition cost" means the price for a drug product listed as the wholesaler acquisition cost in the department's primary price reference source.

(14) "Wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail pharmacies in California.

(b) (1) Reimbursement to Medi-Cal pharmacy providers for legend and non-legend drugs shall consist of the estimated acquisition cost of the drug plus a professional fee for dispensing. The professional fee shall be seven dollars and twenty-five cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility shall be eight dollars ($8) per dispensed prescription. For purposes of this paragraph "skilled nursing facility" and "intermediate care facility" shall have the same meaning as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

(2) The department shall establish the estimated acquisition cost of legend and non-legend drugs as follows:

(A) For single source and innovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, **average acquisition price,** the selling price, the federal upper limit, or the MAIC.

(B) For non-innovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, **average acquisition price,** the selling price, the federal upper limit, or the MAIC.

(3) For purposes of paragraph (2), the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall establish a MAIC only when three or more generically equivalent drugs are available for purchase and dispensing by retail pharmacies in California.

(A)The department shall update the list of MAICs and establish additional MAICs in accordance with all of the following:

(A) The department shall base the MAIC on the mean of the average manufacturer's price of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(B) If average manufacturer prices are unavailable, the department shall establish the MAIC in either of the following ways:

(i) Based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.

(ii) Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.

(C) The department may enter into contracts with a vendor for the purpose of this section on a bid or non-bid basis. In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into on a non-bid basis shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(D) The department shall update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

(E) The department shall establish a process for providers to seek a change to a specific MAIC when the providers believe the MAIC does not reflect current available

market prices. If the department determines a MAIC change is warranted, the department may update a specific MAIC prior to notifying providers.

(F) In determining the average purchase price, the department shall consider the provider-related costs of the products that include, but are not limited to, shipping, handling, storage, and delivery. Costs of the provider that are included in the costs of the dispensing shall not be used to determine the average purchase price.

(4) For purposes of paragraph (2), the department may establish average acquisition price for single source, innovator multiple source drugs and non-innovator multi source drugs.

(A)The department may, at its discretion, establish average acquisition price in one of the following ways;

(i) Based on the volume weighted average acquisition price adjusted by the department to ensure that the average acquisition price represents the average purchase price paid by retail pharmacies in California;
(ii) Based on a national pricing benchmark obtained from the Centers for Medicare and Medicaid Services or on a similar benchmark listed in the department's primary price reference source adjusted by the department to ensure that the average acquisition price represents the average purchase price paid by retail pharmacies in California; or
(iii) Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, from any of the following; providers, wholesalers or drug manufacturers and calculating a proposed average acquisition price.

(B) (i)Providers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition price. Providers shall submit invoice prices and all current and future discounts, rebates and refunds known to the provider that would apply to the acquisition cost of drug products.
(ii)Providers who fail to submit drug price information to the department or a vendor designated by the department as required by this subparagraph shall be subject to immediate suspension under Section 14124.2.

(C) Drug manufacturers and wholesalers shall submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition price.
(i) Drug price information shall include, but not be limited to, unit sales of a drug product to retail pharmacies in California divided by the total number of units of the drug sold by the wholesaler or manufacturer in specified period of time determined by the department. The unit sales information shall be net of any price concessions such as volume, prompt pay, rebates, refunds and cash

discounts known to manufacturers and wholesalers that would apply to retail pharmacy sales.
(ii) Drug products, from manufacturers and wholesalers who fail to submit drug price information to the department or a vendor designated by the department for the purposes of establishing the average acquisition price, may not be a reimbursable benefit of the Medi-Cal program until such time the department has established average acquisition cost price for those drug products.

(D) Drug pricing information provided by individual providers, wholesalers and manufacturers to the department or a vendor designated by the department for the purposes of establishing average acquisition price, pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(E) If implementation of average acquisition price results in lower aggregate drug reimbursement to providers, the department shall consider a one-time adjustment to the dispensing fee. This one-time adjustment in the dispensing fee shall not exceed the aggregate savings associated with the implementation of average acquisition price.

(F) When the department implements average acquisition price,the department shall update the Medi-Cal claims processing system to reflect the average acquisition price of drugs not later than 30 days after the Department has established average acquisition price pursuant to paragraph (4)(A).

(c) **When the department implements selling price** ~~T~~**t**he department shall update the Medi-Cal claims processing system to reflect the selling price of drugs not later than 30 days after receiving the average manufacturer's price.

(d) In order to maintain beneficiary access to prescription drug services, no later than 30 days after the department initially implements selling price as a component of estimated acquisition cost, pursuant to paragraph (2) of subdivision (b), the department shall make a one-time adjustment to the dispensing fees paid to pharmacy providers in accordance with paragraph (1) of subdivision (b). This change shall only be made if selling price results in a lower aggregate drug reimbursement. Any increase in dispensing fee made pursuant to this subdivision shall not exceed the aggregate savings associated with the implementation of selling price. At least
30-days prior to implementing the dispensing fee increase, the department shall issue a copy of the department's request for federal approval pursuant to subdivision (e), to the chairperson in each house that considers appropriations and the Chairperson of the Joint Legislative Budget Committee, or whatever lesser time the Chairperson of the Joint Legislative Budget Committee or his or her designee may determine.

(e) The director shall implement this section in a manner that is consistent with federal Medicaid law and regulations. The director shall seek any necessary federal approvals for the implementation of this section. This section shall be implemented only to the extent that federal approval is obtained.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may **implement, interpret, or make specific this section** ~~take the actions specified in this section~~ by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

(g) The department shall issue a Medi-Cal pharmacy reimbursement fact sheet to the chairperson of the committee in each house of the Legislature that considers appropriations no later than March 1, 2008. The reimbursement fact sheet shall contain, but not be limited to, available data and information regarding the change in reimbursement due to the federal Deficit Reduction Act of 2005 implementation of average manufacturer's price based federal upper limits, the implementation of selling price, change in the average wholesale price reported to the department by the primary price reference source, change in pharmacy dispensing fees, prescription drug volume trends, and the number of active Medi-Cal pharmacy providers. The fact sheet shall also contain general information and definitions regarding drug pricing terminology and a description of pharmacy claims processing in Medi-Cal.

(h) The department may enter into contracts with a vendor for the purpose of this section on a bid or non-bid basis. In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into to implement this section, and all contract amendments and change orders thereto, shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(i) (1) The rates provided for in this section shall be implemented only if the Director determines that the rates, as established by this section, will comply with applicable federal Medicaid requirements and that federal financial participation will be available.

(2) In assessing whether federal financial participation is available, the Director shall determine whether such rates comply with applicable federal Medicaid requirements, including those set forth in 42 United States Code Section 1396a(a)(30)(A). To the extent that the Director determines that the rates do not comply with the federal Medicaid requirements, the Director retains the discretion not to implement that rate and may revise the rate as necessary to comply with the federal Medicaid requirements.

(j) The Director shall seek any necessary federal approval for the implementation of this section. To the extent that federal financial participation is not available

with respect to any rate of reimbursement described by this section, the Director retains the discretion not to implement that rate and may revise the rate as necessary to comply with the federal Medicaid requirements.

(k) Nothing in this section shall be read as requiring the department to collect cost data, to conduct cost studies, or to set or adjust a rate of reimbursement based on cost data that has been collected.
(l) Adjustments to pharmacy drug product reimbursement made pursuant to section 14105.192 shall no longer apply when the Department determines average acquisition price has been fully implemented.

Section 14105.455 of the Welfare & Institutions Code is amended to read:

(a) Pharmacy providers shall submit their usual and customary charge when billing the Medi-Cal program for prescribed drugs.
(b) "Usual and customary charge" means the lower of the following:
(1) The lowest price reimbursed to the pharmacy by other third-party payers in California, excluding Medi-Cal managed care plans and Medicare Part D prescription drug plans.
(2) The lowest price routinely offered to any segment of the general public.
(c) Donations or discounts provided to a charitable organization are not considered usual and customary charges.
(d) Pharmacy providers shall keep and maintain records of their usual and customary charges for a period of three years from the date the service was rendered.
(e) Payment to pharmacy providers shall be the lower of the pharmacy's usual and customary charge or the reimbursement rate pursuant to subdivision (b) of Section 14105.45.
(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may **implement, interpret, or make specific this section** ~~take the actions specified in this section~~ by means of a provider bulletin or notice, policy letter, or other similar instructions, without taking regulatory action.

Section 14105.451 of the Welfare & Institutions Code is amended to read:

14105.451. (a) (1) The Legislature finds and declares all of the following:
(A) The United States Department of Health and Human Services has identified the critical need for state Medicaid agencies to establish pharmacy reimbursement rates based on a pricing benchmark that reflects actual acquisition costs.
(B) The Medi-Cal program currently uses a methodology based on average wholesale price.

(C) Investigations by the federal Office of Inspector General have found that average wholesale price is inflated relative to average acquisition cost.
(2) Therefore, it is the intent of the Legislature to enact legislation by August 1, 2011, that provides for development of a new reimbursement methodology that will enable the department to achieve savings while continuing to reimburse pharmacy providers in compliance with federal law.
(b) The department may require providers, manufacturers, and wholesalers to submit any data the director determines necessary or useful in preparing for the transition from a methodology based on average wholesale price to a methodology based on actual acquisition cost.
(c) In the event that the average wholesale price ceases to be listed by the department's primary price reference source vendor, the department may direct the fiscal intermediary to establish a process with the primary price reference source vendor to report average wholesale price (AWP), consistent with the definition of AWP stated in section 14105.45. If such a process is established by the fiscal intermediary and primary price reference source vendor, it shall be temporary and limited in scope and duration, and cease when the department has fully implemented an average acquisition cost reimbursement methodology pursuant to 14105.45.